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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,657	01/16/2002	William Dawson	U 013830-8	1050

7590

12/22/2004

Ladas & Parry  
26 West 61 Street  
New York, NY 10023

EXAMINER

LEVY, NEIL S

ART UNIT PAPER NUMBER

1616

DATE MAILED: 12/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

10/046,657

**Applicant(s)**

DAWSON, WILLIAM

**Examiner**

Neil Levy

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 9/9/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14, 16-38, 40-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-14, 16-38, 40-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16, 18, 19, 37 is/are rejected.
- 7) ☒ Claim(s) 38 is/are objected to.
- 8) ☒ Claim(s) 1-14, 16-38, 40-42 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 7-9, 16-36, 40-42 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed ~~2/1~~ 8.

Claims 1-6, 10-14, 37 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Henshaw – WO 97/35470.

The rejection of record is maintained. Applicant's amendment, while specifying 100% survival does not specify a minimum initial period. Henshaw shows this period to be determinable, as is the test dosage; both features are art recognized parameters determinable in dose response studies of acute and sub acute bases to determine test dose ranges for further study of efficacy and toxicity. The further studies selected either because of a predetermined test parameter of concern, or mandated by regulatory authority. In this case, body weight change was a parameter of concern. A Dose providing expectation of weight loss was first determined, and non-toxic doses were set aside while higher doses could be examined further. Here, the study expectation period is 14 days. Henshaw goes on to address the testing regimen as suitable for like materials (p.6, lines 28-36). The difference between the invention cited and the instant are in the framing of the question; the procedures are the same. One of ordinary skill in the art of testing for rodenticides would have it within their purview to identify

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criteria of interest, such as body weight loss, and other testing normally performed routinely in animal toxicity efficacy studies. The % body weight loss or % change of organs are obvious parameters one identifies in such testing, with a particular cut off determinable as desired – 20, 25 or 30% are thus determinable cut off points one would identify in an initial study, and be adjustable responsive to desired study period and dose.

Claims 1, 5, 6, 10-14, 31 are anticipated, as Henshaw used corn cob derived celluloses to determine the weight loss, and ultimate rodenticidal effects.

Claims 1-6, 10-14, 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takashi and Henshaw in view of NCI '76.

The rejection of record is maintained. The instant claims are those of standard protocols one in the pharmacological and toxicological arts utilize to determine safety, efficacy and toxicity.

Applicant's arguments filed on 9/9/04 have been fully considered but they are not persuasive. Applicant's intended response falls short, by 5 days, of inserting the examiner indicated bases for allowance over the prior art of record. Reconsideration results in identification of claims to the specific ingredients already known and patented as rodenticidal (claim 11-14), and within normal parameters of toxicity testing. The question of: is this toxic? versus what is toxic? Is seen as an issue for patentability determination. As claimed, we find the screening methods, incorporating standard protocols, as at least obvious in the pesticidal arts.

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Claim 38 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (571) 272-0619. The examiner can normally be reached on Tuesday through Friday 7 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gray Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Levy/LR  
December 1, 2004

**NEIL S. LEVY**  
**PRIMARY EXAMINER**